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# **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

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# **Food and Drug Administration**

[Docket No. 98 N-0864]

Privacy Act of 1974; Altered System of Records, Including Addition of Routine Use(s) to an Existing System of Records

**AGENCY:** Department of Health and Human Services (HHS).

**ACTION:** Notification of an altered system of records, including the addition of a new routine use.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974 (Privacy Act), the Department of Health and Human Services (HHS) is publishing notice of a proposal to alter Privacy Act System of Records 09–10–0010 for the "Bioresearch Monitoring Information System, HHS/FDA," including the addition of a new routine use. The major purposes of the proposed alterations are to add the names of the Center for Food Safety and Applied Nutrition (CFSAN), and the Center for Veterinary Medicine (CVM), and related information regarding these Centers, to ensure that the system covers all of the Food and Drug Administration's (FDA's) Centers; update the relevant statutory and regulatory citations; and modify the routine uses section of the existing system notice by removing unnecessary routine uses, revising other routine uses to bring them in conformance with case law, and adding a new routine use providing for disclosure of covered records to sponsors and Institutional Review Boards (IRB's) involved with studies affected by a clinical investigator's violative or potentially violative conduct.

**DATES:** Submit written comments on the proposed alterations, including the new routine use, by (insert date 30 days after date of publication in the **Federal Register**). HHS sent a Report of Altered System to the Congress and the Office of Management and Budget (OMB) on (insert date of publication in the **Federal Register**). The alteration to the system of records will be

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effective 40 days from the date submitted to OMB unless HHS receives comments which would result in a contrary determination.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Regulatory Counsel (HFC–230), Office of Regulatory Affairs, Office of Enforcement, Division of Compliance Policy, Food and Drug Administration, 12720 Twinbrook Pkwy., suite 517, Rockville, MD 20852, 301-827–0412.

**SUPPLEMENTARY INFORMATION:** FDA proposes to alter Privacy Act System of Records 09– 10-0010 for the 'Bioresearch Monitoring Information System, HHWFDA." The major purposes of the proposed alterations are to: (1) Add the names of CFSAN, and CVM, and related information regarding these Centers, to ensure that the system covers all of FDA's Centers: (2) update the relevant statutory and regulatory citations: and (3) modify the routine uses section of the existing system notice by removing unnecessary routine uses, revising other routine uses to bring them in conformance with case law, and adding a new routine use providing for disclosure of covered records to sponsors and IRB's involved with studies affected by a clinical investigator's violative or potentially violative conduct.

The records in this system will be maintained in a secure manner compatible with their content and use. All records are kept in secured areas, locked rooms, and locked buildings. Manual and computerized records will be maintained in accordance with the standards of Chapter 45– 13 of the HHS General Administration Manual, "Safeguarding Records Contained in Systems of Records," supplementary Chapter PHS hf: 45–13 of the Department's General Administration Manual, and the Department's Automated Information Systems Security Handbook. Data stored in computers will be accessed through the use of regularly expiring passwords and individual ID's known only to authorized users.

FDA staff will be required to adhere to the provisions of the Privacy Act (5 U.S.C. 552a) and the HHS Privacy Act regulations (45 CFR 5b). Only authorized users whose official duties

require the use of such information will have regular access to the records in this system.

Authorized users are FDA employees and contractors responsible for training the individuals who will inspect the facilities of the clinical investigators, who compile and analyze the inspectional data and information, or who, as a part of their official duties, routinely disclose information under the Freedom of Information Act (FOIA) or conduct other authorized sharing of FDA records. Users will be required to sign an agreement indicating their cooperation with FDA systems security and Privacy Act policies.

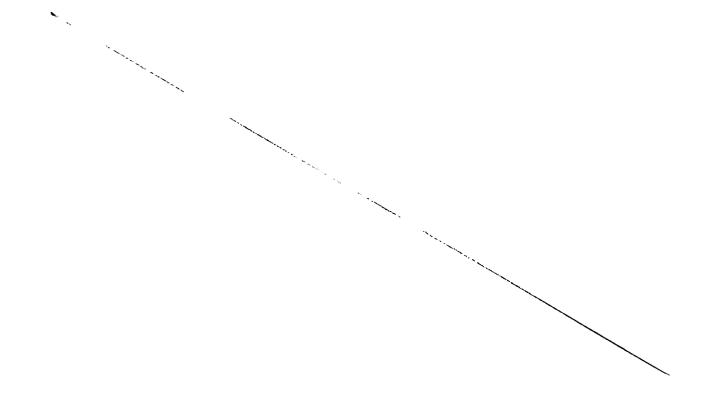
The proposed alteration contains a new routine use permitting disclosure of records in the system to sponsors and IRB's associated with the clinical investigator's studies. Under the altered system, FDA may disclose to sponsors and IRB's those records that on their face, or in conjunction with other records, indicate a violation or potential violation of the law by clinical investigators that have conducted or are conducting studies. Disclosure would be made either under a request from the sponsor or IRB or, in FDA's discretion, without the need for a request. The purpose of disclosure would be to alert these parties to inspectional findings indicating violations or potential violations of the laws enforced by FDA, including the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.) and its implementing regulations. Such disclosure is compatible with the purpose of the system because the sponsors and IRB's play a significant role in ensuring that clinical investigators meet the applicable statutory and regulatory requirements. Disclosure also provides the sponsors and IRB's with information that is important to meeting their responsibilities under FDA's regulations, including their responsibility to monitor the data collected under the study.

In some cases, evidence of a violation or potential violation may implicate more than one of the clinical investigator's studies. Where more than one clinical study is involved, FDA may, where it deems appropriate, share information concerning a violation or potential violation with the sponsors and IRB's of any of the clinical investigator's studies.

In addition to creating a new routine use, the proposed alteration will delete as unnecessary two routine uses which provide for disclosure of records to certain employees of the agency for use in performance of their duties, thereby duplicating another Privacy Act exemption, 5 U.S.C. 552a(b)(l). The proposed alteration also will revise language in the remaining routine uses to bring them in conformance with recent case law. (See *Covert v. Barrington*, 876 F.2d 751 (9th Cir. 1989).) Minor editorial revisions also have been made throughout the system notice to enhance its clarity and specificity, and to accommodate normal updating changes.

Interested persons may, on or before (insert date 30 days after date of publication in the **Federal Register**), submit to the Dockets Management Branch (address above) written comments regarding the revised system notice. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

The following notice is written in the present, rather than the future tense, to avoid the unnecessary expenditure of public funds to republish the notice after the alteration and routine



use has become effective. The revised system notice, including the proposed alterations, is set forth in full below.

Dated:

October 9, 1998

William K. Hubbard

Associate Commissioner for Policy Coordination

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[FR Doc. 98\_???? Filed ??\_??\_98; 8:45 am]

BILLING CODE 4160-01-F

## **Revised System Notice**

09-10-0010

## **SYSTEM NAME:**

Bioresearch Monitoring Information System, HHS/FDA.

#### **SECURITY CLASSIFICATION:**

None.

#### **SYSTEM LOCATION:**

Center for Biologics Evaluation and Research (CBER), Office of Compliance and Biologics Quality, Bioresearch Monitoring Team (HFM–650), 1401 Rockville Pike, Rockville, MD 20852.

Center for Devices and Radiological Health (CDRH), Office of Compliance, Division of Bioresearch Monitoring (HFZ-3 10), 2094 Gaither Rd., Rockville, MD 20850.

Center for Drug Evaluation and Research (CDER), Office of Compliance, Division of Scientific Investigations (HFD-340), 7520 Standish Pi., Rockville, MD 20855.

Center for Food Safety and Applied Nutrition (CFSAN), Office of Premarket Approval, Division of Product Policy (HFS-205), 200 C St. SW., Washington, DC 20204,

Center for Veterinary Medicine (CVM), Office of Surveillance & Compliance (HFV–234), Division of Compliance, Bioresearch Monitoring Staff, 7500 Standish Pi., Rockville, MD 20855.

## CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Clinical investigators who are conducting, or have conducted, clinical studies of new drugs, biologics, and devices under investigational new drug and biologics, and investigational device exemption requests; clinical investigators who are conducting, or have conducted, studies on food or color additives, generally recognized as safe (GRAS) substances, or infant formula; and clinical investigators who are conducting, or have conducted, studies on new animal drugs under investigational new animal drug requests.

## CATEGORIES OF RECORDS IN THE SYSTEM:

Automated file is maintained on all clinical investigators; contains name, education, professional qualifications and background, Program Oriented Data Systems (PODS) locator code, and information on studies conducted. Manual file contains, in addition to that same information, investigatory material collected by, or developed by, the Food and Drug Administration (FDA), during investigations of possible violations of statutes and regulations governing new drug, biologic, food or color additive, GRAS substance, infant formula, new animal drug, and/or device studies.

#### **AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Section 505(i)(3), Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)(3)), 21 CFR part312 (new drugs and biologics for investigational use); Section 520, Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j), 21 CFR part812 (new devices for investigational use); Sections512('j) and (1)(1), Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(j) and (1)(l)), 21 CFR part511 (new animal drugs for investigational use); Sections 409 and 721, Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348 and 379e), 21 CFR part71 (color additive petitions), 21 CFR part 171 (food additive petitions); Section 412, Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a) (infant formula requirements); and Section 351, Public Health Service Act (42 U.S.C. 262).

## PURPOSE(S) OF THE SYSTEM:

- 1. To provide controls to assure that investigators meet requirements of the relevant statutes and regulations governing new drug, biologic, food or color additive, GRAS substance, infant formula, new animal drug, and/or device studies.
- **2. To serve** as a data base for the effective performance of activities necessary for the conduct of the bioresearch monitoring program.

# ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Records that, on their face or in conjunction with other records, indicate a violation or potential violation of law, may be: (1) Referred for investigation and possible enforcement action under the applicable

Federal, State, or foreign laws to the Department of Justice and other appropriate Federal agencies, an appropriate State food and drug enforcement agency or licensing authority, or the government of a foreign country where studies are being or have been conducted; or (2) disclosed to sponsors or IRB's responsible for initiating, approving, monitoring, or overseeing any studies affected by the violation or potential violation, if the information disclosed is relevant to any enforcement, regulatory, investigative, or prosecutorial responsibility of the receiving entity.

- 2. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the written request of that individual.
- 3. The Department of Health and Human Services (HHS) may disclose information from this system of records to the Department of Justice, or to a court or other adjudicative body, when:
  - (a) HHS, or any component thereof; or
  - (b) any HHS employee in his or her official capacity; or
- (c) any HHS employee in his or her individual capacity where the Department of Justice (or HHS, where it is authorized to do so) has agreed to represent the employee; or
- (d) the United States or any agency thereof (where HHS determines that the litigation is likely to affect HHS or any of its components),

is a party to litigation or has an interest in such litigation, and HHS determines that the use of such records by the Department of Justice, the court or other adjudicative body, is relevant and necessary to the litigation and would help in the effective representation of the governmental interest, provided, however, that in each case, HHS determines that such disclosure is compatible with the purpose for which the records were collected.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

#### STORAGE:

Manual files of investigatory materials are maintained in letter-size manila folders and on microfilm.

Automated fries are maintained on magnetic disk or tape.

#### **RETRIEVABILITY:**

Indexed by name or code number.

#### **SAFEGUARDS:**

- 1. Authorized users: Personnel in CBER's Bioresearch Monitoring Team and CBER Product Review Offices; Personnel in CDRH's Division of Bioresearch Monitoring; Personnel in CDER's Division of Scientific Investigations, Division of Drug Information Resources, Management and Data Systems Branch; Personnel in CFSAN'S Division of Product Policy, Division of Health Effects Evaluation; and Personnel in CVM'S Division of Compliance, Bioresearch Monitoring Staff.
- 2. Physical safeguards: Files are stored in secured areas, locked buildings, locked rooms, locked tape vaults, and lockable data media cabinets.
- 3. Procedural (or technical) safeguards: Limited access and computer password which is changed periodically.
- 4, Implementation guidelines: These practices are in compliance with the standards of chapter 45–13 of the HHS General Administration Manual, "Safeguarding Records Contained in Systems of Record s," supplementary Chapter PHS hf: 45–13, and the Department's Automated Information System Security Handbook.

#### RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the FDA Records Control Schedule transmittal number H:90–1, Departmental number B–331,

## SYSTEM MANAGERS AND ADDRESSES:

Director, Division of Inspections and Surveillance (HFM–650), Center for Biologics Evaluation and Research, Office of Compliance and Biologics Quality, 1401 Rockville Pike, Rockville, MD 20852.

Director, Division of Bioresearch Monitoring (HFZ–3 10), Office of Compliance, Center for Devices and Radiological Health, 2094 Gaither Rd., Rockville, MD 20850.

Deputy Director, Division of Scientific Investigation (HFD-34 1), Center for Drug Evaluation and Research, Office of Compliance, 7520 Standish Pi., Rockville, MD 20855.

Bioresearch Monitoring Project Manager (HFS–207), Center for Food Safety and Applied Nutrition, Office of Premarket Approval, Division of Product Policy, 200 C St. SW., Washington, DC 20204.

Manager, Bioresearch Monitoring Program (HFV–234), Center for Veterinary Medicine, Division of Compliance, 7500 Standish PI., Rockville, MD 20855.

#### NOTIFICATION PROCEDURES:

An individual may learn if a record exists about him or her upon written request with notarized signature or certification of identification under penalty of perjury if request is made by mail, or with identification if request is made in person (see also 21 CFR 21.44), directed to:

FDA Privacy Act Coordinator (HFI–30), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

#### RECORD ACCESS PROCEDURES:

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. Access to record systems which have been granted an exemption from the Privacy Act access requirement may be made at the discretion of the system manager. If access is denied to requested records, an appeal may be made to:

Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

You may also request an accounting of disclosures that have been made of your record, if any.

## **CONTESTING RECORD PROCEDURES:**

Contact the official at the address specified under notification procedures above and reasonably identify the record, specify the information being contested, the corrective action sought, and your reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant.

## **RECORD SOURCE CATEGORIES:**

Individual on whom the record is maintained. Some material is obtained from third parties, e.g., drug companies, publications, or is developed by FDA.

## SYSTEMS EXEMPTED FROM CERTAIN PROWSIONS OF THE ACT:

This system is exempt from access and contest and certain other provisions of the Privacy Act (5 U.S.C. 552a(c)(3), (d)(1) to (d)(4), (e)(3), (c)(4)(G) to (c)(4)(H) and (f)) to the extent that it includes investigatory material compiled for law enforcement purposes, where access would be likely to prejudice the conduct of the investigation.

[FR Dec. 98-???? Filed ??-??-98; 8:45 am]

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